UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/084,844	02/25/2002	Juan Yguerabide	11032-018-999	7432

			EXAMINER
20583	7590	12/19/2005	YU, MELANIE J

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ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on <u>*28 September 2005*</u>.

2a)☒ This action is **FINAL**.   2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,16-20,27,29-36 and 38* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,16-20,27,29-36 and 38* is/are rejected.

7)☒ Claim(s) *38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on <u>*25 February 2002*</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

        1.☐ Certified copies of the priority documents have been received.

        2.☐ Certified copies of the priority documents have been received in Application No. _____.

        3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

DETAILED ACTION

1.   Applicant's amendment filed 28 September 2005 has been entered. Claims 1-3, 5-15, 21-26, 28 and 37 are canceled. Claims 4, 16-20, 27, 29-36 and 38 are new. Claims 4, 16-20, 27-36 and 38 are currently pending in this application.

Withdrawn Rejections

2.   Previous rejections under 35 USC 112, second paragraph and 35 USC 103(a) have been withdrawn in light of applicant's amendment.

Claim Objections

3.   Claim 38 is objected to because of the following informalities: the claim recites "applying at least one at least one optical filter" in line 2 of the claim. It appears this statement should be "applying at least one optical filter". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4.   Claims 4, 16-20, 27-36 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites "one or more assay sites" in part a, "at least one of said at least one assay site" in part b of the claim, and "said one or more assay sites" in part c of the claim. It is unclear whether all assay sites are intended to be the same or whether the optical filter is applied to assay sites different from those recited in parts a and c of the claim.

Claim 18 recites "the one or more reduced-intensity signals to one or more scaled

signals" it is unclear whether the reduced-intensity signals are intended to be the same signals

detected in part c of claim 1.

With respect to claim 38, "said reduced-intensity scattered light" is recited multiple times

in lines 4-6 of the claim. It is unclear whether said reduced-intensity scattered light is intended

to be the same reduced-intensity integrated scattered light signal as recited in claim 1 or whether

a third set of integrated light signals and a second set of reduced-intensity integrated light signals

are intended to be detected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found

in a prior Office action.

5.   Claims 4, 18, 31-36 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Phillips et al. (US 6,171,793) in view of Chenchik et al. (US 6,287,768).

Phillips et al. teach a method for providing an extended linear dynamic range in an

analyte assay comprising: detecting integrated light signals from one or more assay sites with a

sensor having a dynamic range, wherein the integrated light intensity fluorescence signal

collected from at least one assay site exceeded the dynamic range of the sensor (the probe arrays

comprise a plurality of sites, col. 7, lines 1-8; col. 4, lines 42-47; scanned areas where light was

so intense and exceeded the saturation level and produced a saturated, constant value, col. 9,

lines 13-20; partially invalid data obtained above intensity at which the scanner saturates, col. 9,

lines 46-49; first data set, col. 10, lines 43-45); applying at least one optical filter having an

optical density to provide a reduced-intensity fluorescence integrated light signal that does not

exceed the dynamic range of the sensor, the reduced intensity fluorescence light signal is from at

least one of the at least one assay site that produced an integrated light signal that exceeded the

dynamic range of the sensor (light is detected at a first and second wavelength at each site, col. 4,

lines 42-54, which is performed by including filters to detect at the specified wavelengths col. 6,

lines 58-61, and a linear relationship is present between the signals and the integrated light

intensity fluorescence, col. 9, lines 41-59; col. 9, lines 21-34; filter applied to obtain reduced-

intensity signal at 530 nm, col. 9, line 61-col. 10, line 4; col. 6, lines 58-61); detecting a second

set of integrated light intensity fluorescence signals from the light scattering particles at the one

or more assay sites with the sensor, the second set comprising the reduced-intensity fluorescence

integrated light signals (reduced intensity signals are detected at 530 nm and produces a curve

which is in cutoff for low light intensities and is therefore reduced intensity, col. 10, lines 1-4

and 13-17, second data set, col. 10, lines 45-46); converting the reduced-intensity fluorescence

integrated light signals to a scaled signal using a conversion factor related to the optical density

of the optical filter (col. 4, lines 55-62; conversion factor is calculated from curves produced

from first and second data sets at two different maximum wavelengths, which is related to the

optical density of the optical filter which regulates the maximum wavelength, col. 10, lines 27-

35; correlation calculated, col. 10, lines 49-61); and combining the scaled signal with the first set

of integrated light intensity fluorescence signals to provide an extended dynamic range (col. 9,

lines 50-60; col. 10, lines 62-67). Phillips et al. fail to teach detection of scattered light from

light scattering particles and integrated scattered light signals.

Chenchik et al. teach that either fluorescent markers or light scattering particles can be

used for optical detection (col. 16, lines 36-47), in order to provide labeling for molecules.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the method of Phillips et al., substituting light scattering particles for fluorescent markers as taught by Chenchik, which would result in optical detection of scattered light intensity signals produced by light scattering particles at specified wavelengths instead of optical detection of fluorescent light intensity signals. One having ordinary skill in the art would have been motivated to make such a change as a mere alternative and functionally equivalent detection technique and since only the expected labeling effect would have been obtained. The use of alternative and functionally equivalent techniques would have been desirable to those of ordinary skill in the art based on the economics and availability of components.

Regarding claim 18, Phillips et al. teach converting the one or more reduced-intensity signals to one or more scaled signals by multiplying the one or more reduced intensity signals by the conversion factor of the at least one filter (conversion factor relies on the optical filter used to filter out wavelengths above 530 nm, and therefore conversion factor is related to the optical density of the optical filter, col. 10, lines 26-35).

With respect to claims 31-36, Phillips et al. teach further forming an image of one or more assay sites with the combined scaled signal and first set of integrated light intensity signals (col. 11, lines 15-30, comparison of image result before and after conversion shown in figures 7 and 13, respectively) comprising the steps of identifying background portions of the image and removing signals corresponding to the background portions of the image (background signals are identified and removed from detected signal for reduced-intensity signal, col. 9, lines 35-49). Phillips et al. also teach the sensor being a photomultiplier tube (col. 6, lines 51-57). Phillips et

al. further teach a the at least one or more assay sites being separately addressable assay sites

(col. 6, lines 62-67), associated with a microarray (col. 5, lines 49-53), and present in a sample of

a cell (col. 8, lines 42-51).

Regarding claim 38, Phillips et al. teach after a step of detection a second integrated

signal, repeating: applying at least one optical filter having an optical density that is different

than the at least one optical filter to provide a reduced-intensity integrated light signal that does

not exceed the dynamic range of the sensor, the reduced-intensity light signal from at least one of

the at least one assay sites that produced an integrated light signal that exceeded the dynamic

range of the sensor; and detecting another set of integrated light intensity signals from the light at

the one or more assay sites with the sensor, the another set comprising the reduced-intensity

integrated light signals of the repeated step (if it is desired to further increase the dynamic range

three or more scans with the wavelength at suitably selected different values, therefore an optical

filter with a different optical density would be applied to provide a reduced intensity integrated

light signal and scanning would provide detection and a data set with the optical filter with a

different optical density, col. 12, lines 39-47).

6.   Claims 16, 17, 19, 20, 27, 29 and 30 are rejected under 35 U.S.C. 103(a) as being

unpatentable over Phillips et al. (US 6,171,793) in view of Chenchik et al. (US 6,287,768), as

applied to claim 4, and further in view of Bartz (US 5,350,922).

Regarding claims 16 and 19, Phillips et al. in view of Chenchik et al., as applied to claim

4, teach a method for providing an extended linear dynamic range in an analyte assay and a

conversion factor determined from a transmission curve for the filter (conversion factor is

determined from a transmission curve that is generated from measurements at 530 nm and 570

nm which are provided using an optical filter, therefore the conversion factor is determined

based on a transmission curve for the filter, col. 10, lines 26-35) based on measurements of

transmission of light through the filter (filter is used to generate a curve for 530 nm, col. 6, lines

58-61). However, Phillips et al. fail to teach one or more of the filters being a bandpass

interference filter and a white light source.

Bartz teaches a bandpass interference filter (col. 7, lines 8-12) and a white light source

(col. 6, lines 1-12), in order to pass corresponding wavelength bands by fiber optic probes.

Therefore it would have been obvious to one having ordinary skill in the art at the time

the invention was made to include in the method of Phillips et al., a bandpass interference filter,

a white light source and light from light scattering particles as taught by Bartz, in order to reduce

the optical and electronic signal to noise ratio and provide a precise filter that detects below a

specified wavelength.

Regarding claim 17, the transmission curve for the filter is wavelength dependent

(transmission curve is generated from scanning at 570 nm and 530 nm, and is therefore

wavelength-dependent, col. 10, lines 5-12).

With respect to claim 27, Bartz teaches light transmitted by filters using a white light

source (col. 6, lines 1-12). Bartz further teaches integrated scattered light intensity signals from

light scattering particles comprising light scattered by the light scattering particles (col. 3, lines

26-30).

With respect to claims 29 and 30, Bartz teaches an extended range comprising integrated

scattered light intensity signals quantified over at least six orders of magnitude (col. 3, lines 47-

50), and the dynamic range extended by at least one order of magnitude over the dynamic range

of an assay without the extension of the dynamic range (col. 3, lines 41-50; col. 4, lines 49-54), and the dynamic range being linear (col. 3, lines 41-46).

Regarding claim 20, Phillips et al., as applied to claim 4, fail to teach the amount of light transmitted by one or more filters. However, it has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value for a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation" Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Since applicant has not disclosed that the specific limitations recited in instant claim 20 are for any particular purpose or solve any stated problem, and the prior art teaches that the light transmitted by one or more filters can be varied in order to prevent direct transmission of light from the light source to the detector, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures know in the detection of scattered light art.

Response to Arguments

7.   Applicant's arguments with respect to claims 4, 16-20, 27, 31-36 and 38 have been considered but are moot in view of the new ground(s) of rejection. New ground(s) of rejection is made in view of applicant's amendment requiring detection of scattered light intensity signals.

Regarding Phillips et al. applicant argues that Phillips et al. fail to teach the conversion factor being predetermined and not derived from a calculated correlation function between two measurements of a sample. However, the instant claims fail to recite a conversion factor being predetermined, and merely require that converting signals to a scaled signal requires using a conversion factor related to the optical density of the optical filter. Therefore, since the transmission curves of Phillips et al. used for conversion are produced by detection with an optical filter, the conversion factor of Phillips et al. is related to the optical density of optical filters.

Conclusion

No claims are allowed.

8.   Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The

examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

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12/09/05